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* Admitted only in Maryland
* Admitted only in Virginia
* Practice Limited to Federal Agencies



August 31, 2004

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Art Unit 1632

Re: U.S. Utility Patent Application
Application No. 10/658,688; Filed: September 10, 2003
For: **Codon-Optimized Polynucleotide-Based Vaccines Against *Bacillus anthracis* Infection**
Inventor: Gary G. HERMANSON
Our Ref: 1530.0460002/EJH/J-H

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. Form PTO-1449, 28 pages, listing 147 documents;
3. One (1) copy of cited documents AL1-AN4, and AR1-AR28 (100 documents);
4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

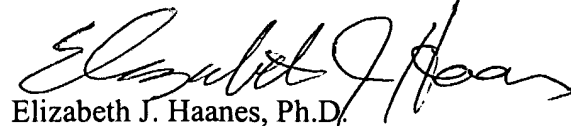
The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

The PTO did not receive the following
listed item(s) CA2,202,322

Commissioner for Patents
August 31, 2004
Page 2

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Elizabeth J. Haanes". The signature is fluid and cursive, with the first name being the most prominent.

Elizabeth J. Haanes, Ph.D.

Attorney for Applicant

Registration No. 42,613

EJH/J-H/tis

298225v1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

HERMANSON

Appl. No.: 10/658,688

Filed: September 10, 2003

For: **Codon-Optimized Polynucleotide-
Based Vaccines Against *Bacillus*
anthracis Infection**

Confirmation No.: 3461

Art Unit: 1632

Examiner: Baskar, P.

Atty. Docket: 1530.0460002/EJH/J-H

Information Disclosure Statement under 37 C.F.R. § 1.97(b)

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of U.S. patents and patent application publications cited on the attached Form PTO-1449 are not submitted in accordance with 1276 OG 55 because this application was filed after June 30, 2003. Copies of documents **AL1** to **AN4** and **AR1** to **AR28** are provided.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following discussion of the relevance of the non-English language documents **AL1-AN1** and **AN3** cited on Form PTO 1449:

Document **AL1** is in a foreign language. An English language abstract of document **AL1** is attached as document **AR27**.

Document **AM1** is in a foreign language. An English language abstract of document **AM1** is attached as document **AR27**.

Document **AN1** is in a foreign language. An English language abstract of document **AN1** is attached as document **AR27**.

Document **AN3** is in a foreign language. An English language abstract of document **AN3** is attached as document **AS27**.

The Examiner's attention is directed to the following copending applications:

U.S. Application No. 09/839,574, inventors Manthorpe *et al.*, filed April 23, 2001, now published as U.S. Published Application No. 2002/0019358 (Document **AJ3**);

U.S. Application No. 10/725,009, inventor Geall, filed December 2, 2003, now published as U.S. Published Application No. 2004/0157789 (Document **AI4**);

U.S. Application No. 10/391,216, inventor Wheeler, C.J., filed March 19, 2003, now published as U.S. Published Application No. 2003/0191082 (Document **AC5**);

U.S. Application No. 10/719,978, inventors Budahazi *et al.*, filed November 24, 2003, now published as U.S. Published Application No. 2004/0157244 (Document **AA5**);

U.S. Application No. 10/725,015, inventors Geall *et al.*, filed December 2, 2003, now published as U.S. Published Application No. 2004/0162256 (Document **AB5**);

U.S. Application No. 10/387,525, inventor Felgner *et al.*, filed March 14, 2003, now published as U.S. Publication Application No. 2004/0023911 (Document **AJ4**);

U.S. Application No. 10/202,858, inventor Felgner *et al.*, filed July 26, 2002, now published as U.S. Publication Application No. 2003/0032615 (Document **AK4**);

U.S. Application No. 10/748,853 (unpublished), inventor Wheeler, C.J., filed December 30, 2003, a copy of which is attached as Document **AT27**;

U.S. Application No. 08/486,533 (unpublished), inventor Felgner, *et al.*, filed June 07, 1995, a copy of which is attached as Document **AR28**; and

U.S. Application No. 09/937,604, inventor Wheeler, C.J., filed September 26, 2001 (National Phase of PCT/US00/08282, published as WO 00/57917, attached as Document **AM3**);

which are directed to related technical subject matter. The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicant has listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may

not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

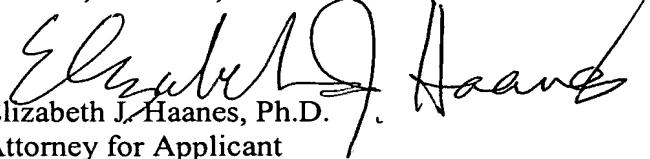
This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

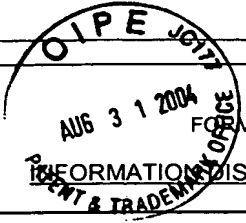
Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.


Elizabeth J. Haanes, Ph.D.
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Date: August 31, 2004

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				Page 1 of 28			
				ATTY. DOCKET NO. 1530.0460002/EJH/JAH			
				APPLICATION NO. 10/658,688			
				FIRST NAMED INVENTOR Hermanson, G.G.			
FILING DATE September 10, 2003				ART UNIT 1632			
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	4,683,195	07/28/1987	Mullis <i>et al.</i>			02/07/1986
	AB1	5,264,618	11/23/1993	Felgner <i>et al.</i>			04/16/1991
	AC1	5,389,540	02/14/1995	Makoff <i>et al.</i>			11/27/1990
	AD1	5,443,966	08/22/1995	Fairweather <i>et al.</i>			08/23/1993
	AE1	5,459,127	10/17/1995	Felgner <i>et al.</i>			09/16/1993
	AF1	5,571,694	11/05/1996	Makoff <i>et al.</i>			07/25/1994
	AG1	5,580,859	12/03/1996	Felgner <i>et al.</i>			03/18/1994
	AH1	5,591,631	01/07/1997	Leppla <i>et al.</i>			02/12/1993
	AI1	5,643,578	07/01/1997	Robinson <i>et al.</i>			01/27/1993
	AJ1	5,677,274	10/14/1997	Leppla <i>et al.</i>			06/25/1993
	AK1	5,747,028	05/05/1998	Calderwood <i>et al.</i>			06/07/1995
FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	CA 2,001,508	04/25/1990	Canada			Yes X No
	AM1	EP 0 366 550 A1	05/02/1990	Europe			Yes X No
	AN1	WO 90/04637 A1	05/03/1990	WIPO			Yes X No
	AO1	WO 94/18332 A2	08/18/1994	WIPO			Yes No
	AP1	WO 94/19482 A1	09/01/1994	WIPO			Yes No
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
	AR	1	Agrawal, A., <i>et al.</i> , "Impairment of dendritic cells and adaptive immunity by anthrax lethal toxin," <i>Nature</i> 424:329-334, Nature Publishing Group (July 2003)				
	AS	1	Aihara, H. and Miyazaki, J-I., "Gene transfer into muscle by electroporation in vivo," <i>Nat. Biotechnol.</i> 16:867-870, Nature America Publishing (1998)				
	AT	1	Anderson, R., <i>et al.</i> , "Immunization of mice with DNA encoding fragment C of tetanus toxin," <i>Vaccine</i> 15:827-829, Elsevier (1997)				
EXAMINER					DATE CONSIDERED		
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.							

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1530.0460002/EJH/JAH	APPLICATION NO. 10/658,688
	FIRST NAMED INVENTOR Hermanson, G.G.	
	FILING DATE September 10, 2003	ART UNIT 1632

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	5,837,693	11/17/1998	German <i>et al.</i>			03/24/1995
	AB2	5,840,312	11/24/1998	Mock <i>et al.</i>			10/19/1994
	AC2	5,861,397	01/19/1999	Wheeler			10/03/1996
	AD2	5,994,317	11/30/1999	Wheeler			04/09/1996
	AE2	6,004,944	12/21/1999	Rothman <i>et al.</i>			10/02/1997
	AF2	6,022,874	02/08/2000	Wheeler			12/23/1998
	AG2	6,224,870	05/01/2001	Segal			01/15/1998
	AH2	6,267,966 B1	07/31/2001	Baillie			08/26/1997
	AI2	6,316,006 B1	11/13/2001	Worsham <i>et al.</i>			11/23/1994
	AJ2	6,387,665 B1	05/14/2002	Ivins <i>et al.</i>			03/07/2000
	AK2	6,379,966 B2	04/30/2002	Monahan <i>et al.</i>			11/29/1999

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	WO 98/08952 A1	05/05/1998	WIPO			Yes No
	AM2	WO 98/11914 A1	03/26/1998	WIPO			Yes No
	AN2	CA 2,202,322	06/20/1998	Canada			Yes No
	AO2	WO 00/02522 A2	01/20/2000	WIPO			Yes No
	AP2	WO 00/02591 A1	01/20/2000	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	2	André, S., <i>et al.</i> , "Increased Immune Response Elicited by DNA Vaccination with a Synthetic gp120 Sequence with Optimized Codon Usage," <i>J. Virol.</i> 72:1497-1503, American Society for Microbiology (1998)
AS	2	Darquet, A.-M., <i>et al.</i> , "A new vehicle for nonviral gene delivery: supercoiled minicircle," <i>Gene Ther.</i> 4:1341-1349, Stockton Press (1997)
AT	2	Davis, H.L., <i>et al.</i> , "Direct gene transfer in skeletal muscle: plasmid DNA-based immunization against the hepatitis B virus surface antigen," <i>Vaccine</i> 12:1503-1509, Elsevier Science (1994)

EXAMINER

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	FIRST NAMED INVENTOR Hermanson, G.G.	
	FILING DATE September 10, 2003	ART UNIT 1632

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3	6,586,409 B1	07/01/2003	Wheeler			03/24/2000
	AB3	6,632,436	10/14/2003	Segal			02/21/2001
	AC3	6,670,332 B1	12/30/2003	Wheeler			06/05/1998
	AD3	6,696,424 B1	02/24/2004	Wheeler			05/26/2000
	AE3	5,589,466	12/31/1996	Felgner <i>et al.</i>			01/26/1995
	AF3	6,214,804 B1	04/10/2001	Felgner <i>et al.</i>			06/07/1995
	AG3	5,703,055	12/30/1997	Felgner <i>et al.</i>			01/26/1994
	AH3	6,710,035 B2	03/23/2004	Felgner <i>et al.</i>			12/02/1999
	AI3	2001/0031264 A1	10/18/2001	Segal			02/21/2001
	AJ3	2002/0019358 A1	02/14/2002	Manthorpe <i>et al.</i>			04/23/2001
	AK3	2002/0045594 A1	04/18/2002	Volkin <i>et al.</i>			09/12/2001

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3	WO 00/56282 A1	09/28/2000	WIPO			Yes No
	AM3	WO 00/57917 A2	10/05/2000	WIPO			Yes No
	AN3	WO 01/19395 A1	03/22/2001	WIPO			Yes X No
	AO3	WO 01/34801 A2	05/17/2001	WIPO			Yes No
	AP3	WO 01/45639 A2	06/28/2001	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>3</u>	Deml, L., <i>et al.</i> , "Multiple Effects of Codon Usage Optimization on Expression and Immunogenicity of DNA Candidate Vaccines Encoding the Human Immunodeficiency Virus Type 1 Gag Protein," <i>J. Virol.</i> 75:10991-11001, American Society for Microbiology (November 2001)
AS	<u>3</u>	Donnelly, J.J., <i>et al.</i> , "DNA Vaccines," <i>Annu. Rev. Immunol.</i> 15:617-648, Annual Reviews Inc. (1997)
AT	<u>3</u>	Duesbery, N.S., <i>et al.</i> , "Proteolytic Inactivation of MAP-Kinase-Kinase by Anthrax Lethal Factor," <i>Science</i> 280:734-737, American Association for the Advancement of Science (1998)

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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1530.0460002/EJH/JAH	APPLICATION NO. 10/658,688
	FIRST NAMED INVENTOR Hermanson, G.G.	
	FILING DATE September 10, 2003	ART UNIT 1632

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA4	2002/0048590 A1	04/25/2002	Klimpel <i>et al.</i>			05/09/2001
	AB4	2002/0051791 A1	05/02/2002	Galloway <i>et al.</i>			12/21/2000
	AC4	2002/0081317 A1	06/27/2002	Mahan <i>et al.</i>			08/09/2001
	AD4	2002/0102277 A1	08/01/2002	Sokol <i>et al.</i>			11/16/2001
	AE4	2002/0142002 A1	10/03/2002	Galloway <i>et al.</i>			03/25/2002
	AF4	2002/0165183 A1	11/07/2002	Herweijer <i>et al.</i>			11/13/2001
	AG4	2002/0197272 A1	12/26/2002	Galloway <i>et al.</i>			03/25/2002
	AH4	2003/0003109 A1	01/02/2003	Galloway <i>et al.</i>			03/25/2002
	AI4	2004/0157789 A1	08/12/2004	Geall			12/02/2003
	AJ4	2004/0023911 A1	02/05/2004	Felgner <i>et al.</i>			03/14/2003
	AK4	2003/0032615 A1	02/13/2003	Felgner <i>et al.</i>			07/26/2002

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL4	WO 02/00844 A2	01/03/2002	WIPO			Yes No
	AM4	GB 2,370,772 A	07/10/2002	Great Britain			Yes No
	AN4	WO 04/024067 A2	03/25/2004	WIPO			Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>4</u>	Felgner, P.L., <i>et al.</i> , "Lipofection: A highly efficient, lipid-mediated DNA-transfection procedure," <i>Proc. Natl. Acad. Sci. USA</i> 84:7413-7417, National Academy of Sciences (1987)
AS	<u>4</u>	Gao, X. and Huang, L., "Potentiation of Cationic Liposome-Mediated Gene Delivery by Polycations," <i>Biochem.</i> 35:1027-1036, American Chemical Society (1996)
AT	<u>4</u>	Gordon, V.M., <i>et al.</i> , "Proteolytic Activation of Bacterial Toxins by Eukaryotic Cells Is Performed by Furin and by Additional Cellular Proteases," <i>Infection & Immunity</i> 63:82-87, American Society for Microbiology (1995)

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U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA5	2004/0157244 A1	08/12/2004	Budahazi <i>et al.</i>			11/24/2003
	AB5	2004/0162256 A1	08/19/2004	Geall <i>et al.</i>			12/02/2003
	AC5	2003/0191082 A1	10/09/2003	Wheeler			03/19/2003
	AD						
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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>5</u>	Gramzinski, R.A., <i>et al.</i> , "Immune Response to a Hepatitis B DNA Vaccine in Aotus Monkeys: A Comparison of Vaccine Formulation, Route, and Method of Administration," <i>Molec. Med.</i> 4:109-118, The Picower Institute Press (1998)
	AS	<u>5</u>	Gu, M.-L., <i>et al.</i> , "Protection against anthrax toxin by vaccination with a DNA plasmid encoding anthrax protective antigen," <i>Vaccine</i> 17:340-344, Elsevier Science Ltd. (1999)
	AT	<u>5</u>	Hammond, S.E. and Hanna, P.C., "Lethal Factor Active-Site Mutations Affect Catalytic Activity In Vitro," <i>Infection & Immunity</i> 66:2374-2378, American Society for Microbiology (1998)

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.
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10/658,688FIRST NAMED INVENTOR
Hermanson, G.G.FILING DATE
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1632**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>6</u>	Hartikka, J., <i>et al.</i> , "An Improved Plasmid DNA Expression Vector for Direct Injection into Skeletal Muscle," <i>Human Gene Ther.</i> 7:1205-1217, Mary Ann Liebert, Inc. (1996)
	AS	<u>6</u>	Hartikka, J., <i>et al.</i> , "Electroporation-Facilitated Delivery of Plasmid DNA in Skeletal Muscle: Plasmid Dependence of Muscle Damage and Effect of Poloxamer 188," <i>Molec. Ther.</i> 4:407-415, The American Society of Gene Therapy (November 2001)
	AT	<u>6</u>	Henderson, D.W., "An Apparatus for the Study of Airborne Infection," <i>J. Hygiene</i> 50:53-68, Cambridge at the University Press (1952)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>1</u>	Holste, D., <i>et al.</i> , "Optimization of Coding Potentials Using Positional Dependence of Nucleotide Frequencies," <i>J. Theor. Biol.</i> 206:525-537, Academic Press (2000)
	AS	<u>1</u>	Horn, N.A., <i>et al.</i> , "Cancer Gene Therapy Using Plasmid DNA: Purification of DNA for Human Clinical Trials," <i>Human Gene Ther.</i> 6:565-573, Mary Ann Leibert, Inc., Publishers (1995)
	AT	<u>1</u>	Ivins, B.E. and Welkos, S.L., "Recent Advances in the Development of an Improved Human Anthrax Vaccine," <i>Eur. J. Epidemiol.</i> 4:12-19, Kluwer Academic Publishers (1988)

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	FIRST NAMED INVENTOR Hermanson, G.G.	
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	AR	<u>8</u>	Ivins, B., <i>et al.</i> , "Experimental anthrax vaccines: efficacy of adjuvants combined with protective antigen against an aerosol <i>Bacillus anthracis</i> spore challenge in guinea pigs," <i>Vaccine</i> 13:1779-1784, Elsevier Science Ltd. (1995)
	AS	<u>8</u>	Klimpel, K.R., <i>et al.</i> , "Anthrax toxin protective antigen is activated by a cell surface protease with the sequence specificity and catalytic properties of furin," <i>Proc. Natl. Acad. Sci. USA</i> 89:10277-10281, National Academy of Sciences (1992)
	AT	<u>8</u>	Kobiler, D., <i>et al.</i> , "Efficiency of Protection of Guinea Pigs against Infection with <i>Bacillus anthracis</i> Spores by Passive Immunization," <i>Infection & Immunity</i> 70:544-550, American Society for Microbiology (February 2002)

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	AR	<u>9</u>	Kushner, N., <i>et al.</i> , "A fragment of anthrax lethal factor delivers proteins to the cytosol without requiring protective antigen," <i>Proc. Natl. Acad. Sci. USA</i> 100:6652-6657, National Academy of Sciences (May 2003)
	AS	<u>9</u>	Leppla, S.H., "Anthrax toxin edema factor: A bacterial adenylate cyclase that increases cyclic AMP concentrations in eukaryotic cells," <i>Proc. Natl. Acad. Sci. USA</i> 79:3162-3266, National Academy of Sciences (1982)
	AT	<u>9</u>	Leppla, S.H., "Production and Purification of Anthrax Toxin," <i>Meth. Enzymol.</i> 165:103-116, Academic Press, Inc. (1988)

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	AR	<u>10</u>	Lindmayer, I., <i>et al.</i> , "Development of New Jet Injector for Insulin Therapy," <i>Diabetes Care</i> 9:294-297, American Diabetes Association (1986)
	AS	<u>10</u>	Little, S.F. and Knudson, G.B., "Comparative Efficacy of <i>Bacillus anthracis</i> Live Spore Vaccine and Protective Antigen Vaccine against Anthrax in the Guinea Pig," <i>Infection & Immunity</i> 52:509-512, American Society for Microbiology (1986)
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	AR	<u>11</u>	Martins, J. and Roedl, E.A., "Medijector - A New Method of Corticosteroid -Anesthetic Delivery," <i>J. Occup. Med.</i> 21:821-824, Williams and Wilkins (1979)
	AS	<u>11</u>	McShane, H., "Prime-boost immunization strategies for infectious diseases," <i>Curr. Opin. Molec. Ther.</i> 4:23-27, PharmaPress Ltd. (February 2002)
	AT	<u>11</u>	Mesnager, S. and Fouet, A., "Plasmid-Encoded Autolysin in <i>Bacillus anthracis</i> : Modular Structure and Catalytic Properties," <i>J. Bacteriol.</i> 184:331-334, American Society for Microbiology (January 2002)

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	AR	<u>13</u>	Mirzabekov, T., <i>et al.</i> , "Enhanced Expression, Native Purification, and Characterization of CCR5, a Principal HIV-1 Coreceptor," <i>J. Biol. Chem.</i> 274:28745-28750, The American Society for Biochemistry and Molecular Biology, Inc. (1999)
	AS	<u>13</u>	Mock, M. and Fouet, A., "Anthrax," <i>Annu. Rev. Microbiol.</i> 55:647-671, Annual Reviews (January 2001)
	AT	<u>13</u>	Nagata, T., <i>et al.</i> , "Codon Optimization Effect on Translational Efficiency of DNA Vaccine in Mammalian Cells: Analysis of Plasmid DNA Encoding a CTL Epitope Derived from Microorganisms," <i>Biochem. Biophys. Res. Commun.</i> 261:445-451, Academic Press (1999)

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	AR	<u>14</u>	Nakamura, Y., <i>et al.</i> , "Codon usage tabulated from international DNA sequence databases: status for the year 2000," <i>Nucl. Acids Res.</i> 28:292, Oxford University Press (2000)
	AS	<u>14</u>	Narum, D.L., <i>et al.</i> , "Codon Optimization of Gene Fragments Encoding <i>Plasmodium falciparum</i> Merzoite Proteins Enhances DNA Vaccine Protein Expression and Immunogenicity in Mice," <i>Infection and Immunity</i> 69:7250-7253, American Society for Microbiology (December 2001)
	AT	<u>14</u>	Nossal, G., "Living up to the legacy," <i>Nat. Med, Vaccine Suppl.</i> 4:475-476, Nature Publishing Company (1998)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>15</u>	Osorio, J.E., <i>et al.</i> , "Immunization of dogs and cats with a DNA vaccine against rabies virus," <i>Vaccine</i> 17:1109-1116, Elsevier Science Ltd. (1999)
	AS	<u>15</u>	Pannifer, A.D., <i>et al.</i> , "Crystal structure of anthrax lethal factor," <i>Nature</i> 414:229-233, Nature Publishing Group (November 2001)
	AT	<u>15</u>	Park, S. and Leppla, S.H., "Optimized Production and Purification of <i>Bacillus anthracis</i> Lethal Factor," <i>Prot. Exp. & Purif.</i> 18:293-302, Academic Press (2000)

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	AR	<u>16</u>	Pellizzari, R., <i>et al.</i> , "Anthrax lethal factor cleaves MKK3 in macrophages and inhibits the LPS/IFN γ -induced release of NO and TNF α ," <i>FEBS Lett.</i> 462:199-204, Elsevier Science B.V. (1999)
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	AT	<u>16</u>	Pezard, C., <i>et al.</i> , "Protective Immunity Induced by <i>Bacillus anthracis</i> Toxin-Deficient Strains," <i>Infection & Immunity</i> 63:1369-1372, American Society for Microbiology (1995)

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	AR	<u>17</u>	Pitt, M.L.M., <i>et al.</i> , "In vitro correlate of immunity in a rabbit model of inhalational anthrax," <i>Vaccine</i> 19:4768-4773, Elsevier Science Ltd. (September 2001)
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	AT	<u>17</u>	Qin, Y.-J., <i>et al.</i> , "Gene Suture - A Novel Method for Intramuscular Gene Transfer and Its Application in Hypertension Therapy," <i>Life Sciences</i> 65:2193-2203, Elsevier Science Inc. (1999)

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	AR	<u>19</u>	Rizzuto, G., <i>et al.</i> , "Gene Electrotransfer Results in a High-Level Transduction of Rat Skeletal Muscle and Corrects Anemia of Renal Failure," <i>Hum. Gene Ther.</i> 11:1891-1900, Mary Ann Liebert, Inc. (2000)
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	AT	<u>19</u>	Schrijver, R.S., <i>et al.</i> , "Immunization of cattle with a BHV1 vector vaccine or a DNA vaccine both coding for the G protein of BRSV," <i>Vaccine</i> 15:1908-1916, Elsevier Science Ltd. (1997)

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	AT	<u>20</u>	Singh, Y., <i>et al.</i> , "Study of Immunization against Anthrax with the Purified Recombinant Protective Antigen of <i>Bacillus anthracis</i> ," <i>Infection & Immunity</i> 66:3447-3448, American Society of Microbiology (1998)

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	AR	<u>21</u>	Toncheva, V., <i>et al.</i> , "Novel vectors for gene delivery formed by self-assembly of DNA with poly(L-lysine) grafted with hydrophilic polymers," <i>Biochim. et Biophys. Acta</i> 1380:354-368, Elsevier Science B.V. (1998)
	AS	<u>21</u>	Trubetskoy, V.S., <i>et al.</i> , "Cationic liposomes enhance targeted delivery and expression of exogenous DNA mediated by N-terminal modified poly(L-lysine)-antibody conjugate in mouse lung endothelial cells," <i>Biochim. et Biophys. Acta</i> 1131:311-313, Elsevier Science Publishers B.V. (1992)
	AT	<u>21</u>	Uchijima, M., <i>et al.</i> , "Optimization of Codon Usage of Plasmid DNA Vaccine Is Required for the Effective MHC Class I-Restricted T Cell Responses Against an Intracellular Bacterium," <i>J. Immunol.</i> 161:5594-5599, American Association of Immunologists (1998)

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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1530.0460002/EJH/JAH	APPLICATION NO. 10/658,688
	FIRST NAMED INVENTOR Hermanson, G.G.	
	FILING DATE September 10, 2003	ART UNIT 1632

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	AR	<u>22</u>	Vahlsing, H.L., <i>et al.</i> , "Immunization with plasmid DNA using a pneumatic gun," <i>J. Immunol. Meth.</i> 175:11-22, Elsevier Science B.V. (1994)
	AS	<u>22</u>	Van Drunen Little-van den Hurk, S., <i>et al.</i> , "Intradermal immunization with a bovine herpesvirus-1 DNA vaccine induces protective immunity in cattle," <i>J. Gen. Virol.</i> 79:831-839, Society for General Microbiology (1998)
	AT	<u>22</u>	Varughese, M., <i>et al.</i> , "Identification of a Receptor-Binding Region within Domain 4 of the Protective Antigen Component of Anthrax Toxin," <i>Infect. & Immun.</i> 67:1860-1865, American Society for Microbiology (1999)

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	AR	<u>23</u>	Wang, R., <i>et al.</i> , "Induction of CD4 ⁺ T cell-dependent CD8 ⁺ type 1 responses in humans by a malaria DNA vaccine," <i>Proc. Natl. Acad. Sci. USA</i> 98:10817-10822, National Academy of Sciences (September 2001)
	AS	<u>23</u>	Welkos, S.L., <i>et al.</i> , "Sequence and analysis of the DNA encoding protective antigen of <i>Bacillus anthracis</i> ," <i>Gene</i> 69:287-300, Elsevier (1988)
	AT	<u>23</u>	Welkos, S., <i>et al.</i> , "The role of antibodies to <i>Bacillus anthracis</i> and anthrax toxin components in inhibiting the early stages of infection by anthrax spores," <i>Microbiol.</i> 147:1677-1685, Society for General Microbiology (June 2001)

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	AR	<u>24</u>	Wheeler, C.J., <i>et al.</i> , "A novel cationic lipid greatly enhances plasmid DNA delivery and expression in mouse lung," <i>Proc. Natl. Acad. Sci. USA</i> 93:11454-11459, National Academy of Sciences (1996)
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	AT	<u>24</u>	Yanisch-Perron, C., <i>et al.</i> , "Improved M13 phage cloning vectors and host strains: nucleotide sequences of the M13mp18 and pUC19 vectors," <i>Gene</i> 33:103-119, Elsevier Science Publishers (1985)

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	AR	<u>25</u>	Zelphati, O., <i>et al.</i> , "Stable and monodisperse lipoplex formulations for gene delivery," <i>Gene Ther.</i> 5:1272-1282, Stockton Press (1998)
	AS	<u>25</u>	Entelechon GmbH, "Backtranslation tool V2.0," available at http://www.entelechon.com/eng/backtranslation.html (downloaded July 2004)
	AT	<u>25</u>	NCBI Entrez, GenBank Report, Accession No. M30210, Lowe, J., (Entry date 1993)

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	AS	<u>27</u>	STNEasy Database, Accession No. 2001:208128, English language abstract for WO 2001019395 A1 (Document No. AN3)
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	AR	<u>28</u>	Copy of Co-Pending U.S. Patent Application No. 08/486,533 (unpublished), inventors Felgner <i>et al.</i> , filed June 07, 1995.
	AS	<u>28</u>	
	AT	<u>28</u>	

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